

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

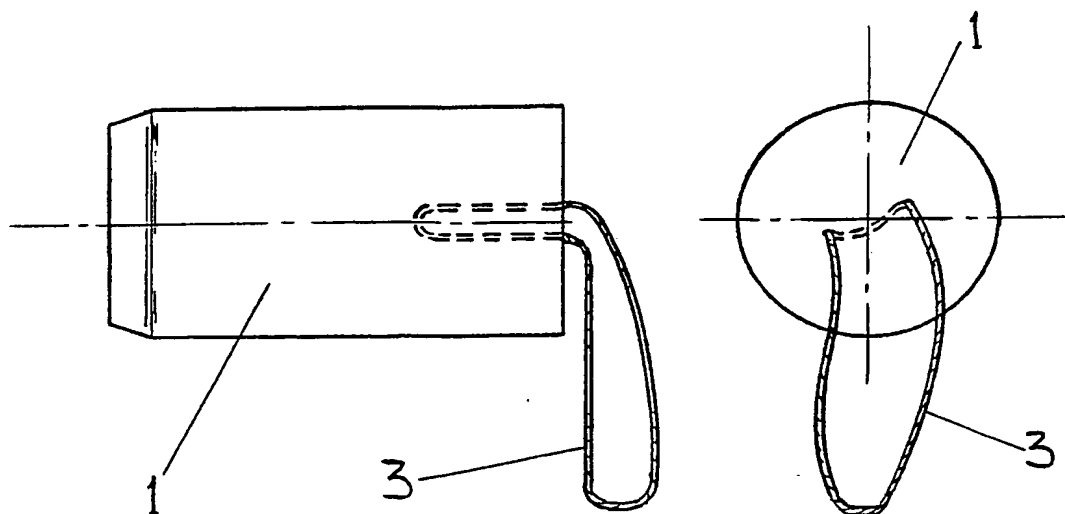


85

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification⁴ : A61F 2/48, 13/20</p>	<p>A1</p>	<p>(11) International Publication Number: WO 88/ 10106 (43) International Publication Date: 29 December 1988 (29.12.88)</p>
<p>(21) International Application Number: PCT/GB88/00464 (22) International Filing Date: 15 June 1988 (15.06.88) (31) Priority Application Number: 8713938 (32) Priority Date: 15 June 1987 (15.06.87) (33) Priority Country: GB (71) Applicant (for all designated States except US): PROSTHEX LTD. [GB/GB]; Bridge Road, Camberley, Surrey GU15 QR (GB). (72) Inventor; and (75) Inventor/Applicant (for US only) : WEST, Hazel, Rowan [GB/GB]; The Old Post Office, Mill Lane, Elmley Castle, Nr. Pershore, Worcestershire WR10 3HP (GB). (74) Agent: GEE & CO.; Chancery House, Chancery Lane, London WC2A 1QU (GB).</p>		<p>(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), LU (European patent), NL (European patent), SE (European patent), US. Published <i>With international search report.</i></p>

(54) Title: FEMALE URINARY INCONTINENCE DEVICE



(57) Abstract

A cylindrical sponge tampon (1) for use in cases of female urinary incontinence is locatable in the vagina (2) and supports the urethra (5a) to prevent leakage during active movement. The sponge tampon (1) is typically 34 mm diameter and 60 mm in length when wet and supports a minimum of 0.28 kg (0.5 lbs) weight when squashed to half its diameter and to not greater than 4.54 kg (10 lbs). The preferred material is a formalised polyvinyl alcohol sponge which is a medically proven material.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	ML	Mali
AU	Australia	GA	Gabon	MR	Mauritania
BB	Barbados	GB	United Kingdom	MW	Malawi
BE	Belgium	HU	Hungary	NL	Netherlands
BG	Bulgaria	IT	Italy	NO	Norway
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland				

- 1 -

FEMALE URINARY INCONTINENCE DEVICE

This invention relates to female urinary incontinence devices.

Female urinary incontinence occurs frequently as reported by Thomas et al in the British Medical Journal, 281, p.1243-45 (9 Nov 1980). A postal questionnaire returned by 9,323 women showed that 8.5% aged 15-64, and 11.6% aged 65 and over, suffered regular urinary incontinence. It was also significant that those women who had given birth to children experienced urinary incontinence to a much greater extent than those with no children.

There are several causes of female urinary incontinence:-

- (1) Perforation of the bladder
- (2) Instability causing premature voiding before the bladder becomes full
- (3) Retention with overflow due to nervous disorder, and
- (4) Stress incontinence

The last category is the most common and results from the inability of the muscles to hold the urethra in a closed condition. Stress incontinence can range from mild to severe. Severe cases are usually treated surgically but surgery is not appropriate for mild cases or where the patient is unable to undergo surgery for medical or other reasons.

- 2 -

It has long been known that stress incontinence in females can sometimes be alleviated by the use of support devices within the vagina. Many patents describe specially shaped devices which in some cases are made
5 of sponge or partly of sponge. These devices support the urethra to prevent leakage during such activities as running, walking, jumping, sneezing and coughing.

A cylindrical sponge tampon for use in urinary
10 incontinence and which is similar in size to the internal suppository tampon used extensively during periods, is made by Rocket Ltd. The Rocket tampon has been found to provide limited assistance for a small number of sufferers from urinary incontinence but it cannot assist
15 a much larger number of women who have to wear sanitary towels and waterproof knickers.

Tampons are also used in the treatment of skin disorders of the vagina. For example, US Patent 3,902,493
20 (Baier and Trokham) describes a medicated tampon having a core of polyurethane foam with a compressibility sufficient only to ensure adequate contact of a medicated surface with the wall of the vagina.

Furthermore, several patents describe rigid
25 or semi-rigid devices specially shaped to press against the wall of the vagina and block the flow of urine through the urethra. These devices are difficult to fit (possibly needing medical assistance) and expensive to manufacture.
30 Moreover, they are also uncomfortable to wear and may cause irritation to the vagina.

The object of this invention is to provide a female urinary incontinence device which gives an adequate
35 degree of support to the urethra but which is easy to

- 3 -

insert and remove, comfortable to wear, of low cost, and of medically acceptable material.

According to the present invention there is provided a female urinary incontinence device comprising a tampon of a sponge material which when compressed in the wet state under conditions hereinafter defined is capable of supporting a weight of at least 0.28 kg (0.5 lb) and not greater than 4.54 kg (10 lb) per 60 mm length, the tampon when located in the vagina acting to support the urethra and thereby prevent leakage of urine therefrom during active movement.

The weight supporting capability of the sponge material was determined at 20°C by compressing a cylinder of sponge material across its diameter of 34 mm between flat plates at a rate of approximately 22 mm per second, allowing a compressed dwell time of 1 minute, and subsequently allowing expansion over a period of 1 second. The above cycle of operations is repeated a further four times with a dwell time in the uncompressed state of 1 second, the measurement being taken on the expansion stroke of the fifth cycle to determine the weight capable of being supported.

Preferably, the material can support a weight of at least 0.45 kg (1 lb) per 60 mm length, and not greater than 2.270 kg (5 lbs) per 60 mm length.

Preferably again, the material is one that maintains its weight supporting capability for long periods of time at body temperature (37.5°C) and in the presence of urine and vaginal fluids. Further, the sponge material is desirably one that when wet provides the minimum change of force when small changes in compression occur,

- 4 -

e.g. 2 mm, due to body movements during walking, running, jumping, coughing and sneezing.

Ideally the tampon should be formed of material
5 which, when compressed to half its diameter between
two flat parallel surfaces at a body temperature of
37.5°C, exerts a force of at least 0.45 kg (1 lb) over
a period of 12 hours, and also when cycled by 2 mm about
10 this compressed state over a period of 12 hours. A
particularly preferred sponge material is a formalised
polyvinyl alcohol sponge material made by PROSTHEX LTD.,
which is a medically proven material. (See Brit. Jnl.
Surgery XLII, 618 (1955) and XLIV, 248 (1956).

15 An embodiment of the invention, together with
comparative tests of sponge material, will now be des-
cribed, by way of example, in relation to the accompanying
drawings in which

20 Fig. 1 is a medial vertical section of the female
body showing a typically-sized tampon according to the
invention in position;

Fig. 2 is a detailed side and end elevation
25 of the tampon of Fig. 1;

Figs. 3 and 4 are graphs of the major hysteresis
loops of force against distance for various wet tampons
of the size shown in Fig. 2 at 20°C and at 45°C respec-
30 tively; and

Fig. 5 is a graph of the minor hysteresis loops
of force against distance for various wet tampons of
the Fig. 2 size at 20°C.

- 5 -

Fig. 1 shows a cylindrical tampon 1 of typical size in position in a vagina 2 and having a loop of string 3 attached thereto and protruding from the vagina to allow easy removal of the tampon 1. The bladder 4 empties via the urethra 5 and the tampon 1 helps to keep the urethra 5 in a closed condition. The uterus 6 is also shown.

Fig. 2 shows the typically-sized tampon 1 having a diameter of 34 mm and length of 60 mm: it may have as shown a slightly reduced diameter at the end remote from the loop 3 to facilitate fitment. Several sizes of tampon (possibly three) are required to suit the range of physical sizes of the vagina. The length is more important and may range from 40 to 80 mm whereas the diameter is less critical and may range from 30 to 38 mm. All these sizes apply in the wet condition.

The selection of sponge material of which the body of the tampon 1 is formed will now be discussed in detail.

Figs. 3 and 4 show, graphically, the hysteresis loops of cylinders of wet sponge material of typical size (34 mm) and various types when compressed across their diameters between flat plates. This test approximately replicates the compressive force applied to the tampon when in position in the vagina. The tests were carried out with the cylinder in a moist condition at both 20°C (Fig. 3) and 45°C (Fig. 4). 45°C was chosen for test purposes so as to slightly exceed body temperature (37.5°C) to allow a safety factor as test conditions were not easy to control ($\pm 5^\circ\text{C}$ estimated).

- 6 -

The hysteresis loops were taken in general accordance with the previously defined conditions as follows:-

Each compression took place over a period of approximately 1 second, i.e. the rate of movement was approximately 22 mm per second. The tampon was then held in a compressed state for various periods of time up to 30 minutes in duration, following which expansion took place over a period of approximately 1 second. Recompression of the tampon to perform a further hysteresis loop was made after a 1 second dwell time in the uncompressed state.

It was found that a reasonably stable hysteresis loop was obtained after five cycles, each with a compressed dwell time of 1 minute in the case of the tests at 20°C. The procedure for the tests at 45°C was slightly modified to allow for cooling of the water bath in which the test sponge was immersed in that the sponge was initially held compressed for five minutes in water at an initial temperature of 50°C, and then cycled five times with a dwell time in the compressed state of only 5 seconds. The curves shown in Figs. 3 and 4 relate to the final (fifth) cycle which, of course, exhibits values substantially lower than those of the first cycles. It is believed that the lower curve portion of the fifth cycle represents a reasonable measure of the performance of the tampon in practice.

A range of different polyurethane and cellulose sponge materials was tested to assess their suitability for use in the present invention and were divided into three categories:-

- 7 -

- A Preferred - provided support for most situations
- B Useful - provided support for some situations
- C Unsuitable - provided inadequate support

5 Typical samples from these three categories
were tested to measure the support force against distance,
and the results are shown in Figs. 3 and 4, the category
A material exhibiting the highest support capability,
category B intermediate capability, and category C the
10 lowest capability.

After a period of time under pressure, the sponge
force was generally at or close to the lower portion
of its hysteresis curve, i.e. the curve obtained during
15 the release of pressure shown by the arrows pointing
to the left in Figs. 3 and 4.

Assuming that 0.45 kg (1 lb) force is required
to provide adequate support for most situations, it
20 will be seen that the following compressed dimensions
are necessary:

	20°C	45°C
25 A	21 mm	21 mm
B	18 mm	16 mm
C	-	-

Category A material easily achieves the 0.45 kg
(1 lb) force.
30

Category B material is adequate at 20°C and
just achieves 0.45 kg (1 lb) at 16 mm compressed dimension
at 37.5°C (body temperature).

- 8 -

It is therefore seen that the sponge in category C is not capable of providing a 0.45 kg (1 lb) force when limited to a 16 mm compressed dimension (separate tests have shown that compression to less than 5 mm would be necessary), and it is not therefore suitable for use in the present invention.

The sponge material of which the previously-mentioned Rocket tampon is formed falls into category C.

The polyurethane foam material used in forming the tampon of US Specification 3,902,493 has a wet modulus of compressibility of foam 70.31 kg/m² (0.1 psi) to 210.93 kg/m² (0.3 psi) according to ASTM D 1564. Experience with such polyurethane foams has shown that such a material exerts only a small force when released from compression and that when tested under test conditions of the present invention would fall into Category C.

It is also important that the maximum force required to compress the tampon should not be excessive to permit ease of insertion into the vagina. The tampon would ideally require less than 2.27 kg (5 lbs) force to compress it to half its diameter, while a maximum force of 4.54 kg (10 lbs) is marginally acceptable.

Fig. 5 gives the results of tests to show the effect of small movements on the support force.

The curves shown in Fig. 5 are known as minor hysteresis loops and are obtained by compressing the sponge to a given point on the hysteresis curve then partly relaxing the compression by a small amount (2 mm).

- 9 -

Several cycles round this minor loop are taken to stabilise it at its lowest level at which time a measurement is taken. Compression and relaxation of the sponge is effected in approximately 0.25 seconds to simulate rapid body movement.

It can be seen that the minor loops lie almost horizontally at low compressions, i.e. only a small change in force occurs for the 2 mm change in compression.

For large compressions, the minor loops become almost vertical, i.e. a large change in force occurs for the 2 mm change in compression. A highly compressed tampon is therefore unsatisfactory in practice as only a small dimensional change will result in a large loss in compressive force. Thus running, jumping, bending or even walking could cause enough movement to release the compressive force.

Three particular minor loops in Fig. 5 are labelled (a), (b) and (c) and correspond with the sponge materials A, B and C. These three minor loops have similar mean values of pressure around 1.5 pounds (0.68 kg). However, for the 2 mm change of compression the three categories of material show widely different reductions in pressure:-

	Material Category	Minor Loop	Reduction in Pressure	
			Pounds	Kg
30	A	(a)	0.8	0.36
	B	(b)	1.2	0.54
	C	(c)	2.4	1.08

Category C material has three times the change of pressure

- 10 -

of Category A material, whilst Category B material is only 50% higher.

5 The size of the tampon is governed primarily
by what is easy and convenient to fit in place and,
moreover, by what is comfortable in use. This size
will thus vary with each person. However, although
a tampon that is easily compressible will obviously
be somewhat easier to fit, it will need to remain in
10 an extremely compressed state in order to provide adequate
support thus leading to an excessive change of compressive
force, with small deflections. At the other extreme,
a rigid tampon will be extremely uncomfortable and will
not yield to conform to the required internal shape
15 so as to apply relatively constant pressure equally
over the area in question.

It is preferred that the tampon be left in place
during the day, it being quite unnecessary to remove
20 it when urinating. However, it should be removed at
night, and washed thoroughly. Obviously for hygienic
reasons it should be used only for a few days before
being discarded. This also helps to guard against the
very rare phenomenon of toxic shock. The requirements
25 for day long wear and frequent renewal demand that the
tampon should be of medically proven material but at
the same time be of low cost and capable of being made
by an economic production process.

30 Sponge materials are generally of polyurethane
or cellulose and a wide range of such commercially avail-
able materials were tested in the search for a suitable
tampon material giving adequate support. None was found
to be satisfactory. Experience with the three categories
35 of tampon sponge material has in fact shown not only

- 11 -

the ideal material is in category A as described above, but also that the only material which adequately conforms to the requirements of category A is a polyvinyl formal sponge produced by Prosthesis Ltd. from polyvinyl alcohol by the action of formaldehyde by a process which yields a cross-bonded polymer having great physical and chemical stability. The sponge is a medically proven material which has been found to be reasonably comfortable for all-day use; impervious to attack by body fluids, in particular urine and vaginal secretions; and to maintain its shape and resilience for long periods. It should be noted that the polyvinyl formal sponge material has a rigid cylindrical shape when completely dry and should be soaked in warm water immediately prior to use. The size of the sponge when dry is smaller than when wet. (It will have been noted that the sizes quoted in this specification all relate to the size when wet.)

- 12 -

CLAIMS:-

1. A female urinary incontinence device comprising a tampon of a sponge material which when compressed in the wet state under conditions hereinbefore defined is capable of supporting a weight of at least 0.28 kg
5 (0.5 lb) and not greater than 4.54 kg (10 lb) per 60 mm length, the tampon when located in the vagina acting to support the urethra and thereby prevent leakage of urine therefrom during active movement.
- 10 2. A device as claimed in claim 1, in which the material is capable of supporting a weight of at least 0.54 kg (1 lb) per 60 mm length.
- 15 3. A device as claimed in claim 1 or 2, in which the material is capable of supporting a weight not greater than 2.270 kg (5 lbs) per 60 mm length.
- 20 4. A device as claimed in claim 1, 2 or 3, in which the material is capable of substantially maintaining its supporting force under conditions of transient movement during a period of one second or less.
- 25 5. A device as claimed in any preceding claim, in which the tampon is of generally cylindrical shape and is from 30 to 38 mm in diameter and from 40 to 80 mm in length.
- 30 6. A device as claimed in any preceding claim, in which the material, when compressed under said conditions and when cycled by 2 mm about such compressed state, exerts a force of at least 0.45 kg (1 lb) over a period of 12 hours.

- 13 -

7. A device as claimed in any preceding claim,
in which the material is a formalised polyvinyl alcohol
sponge material.

1/4

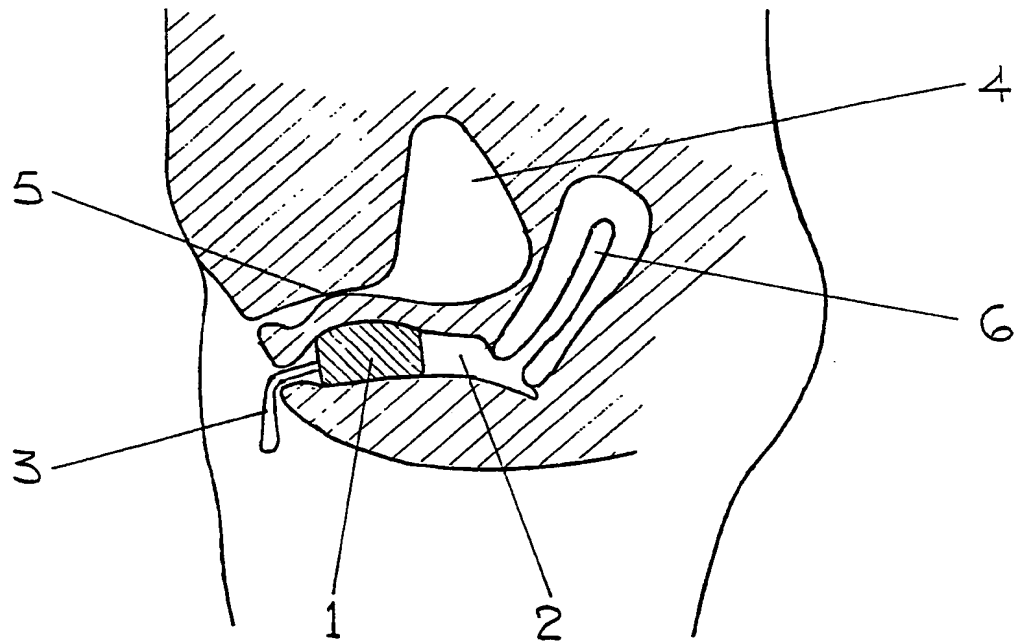


FIGURE 1

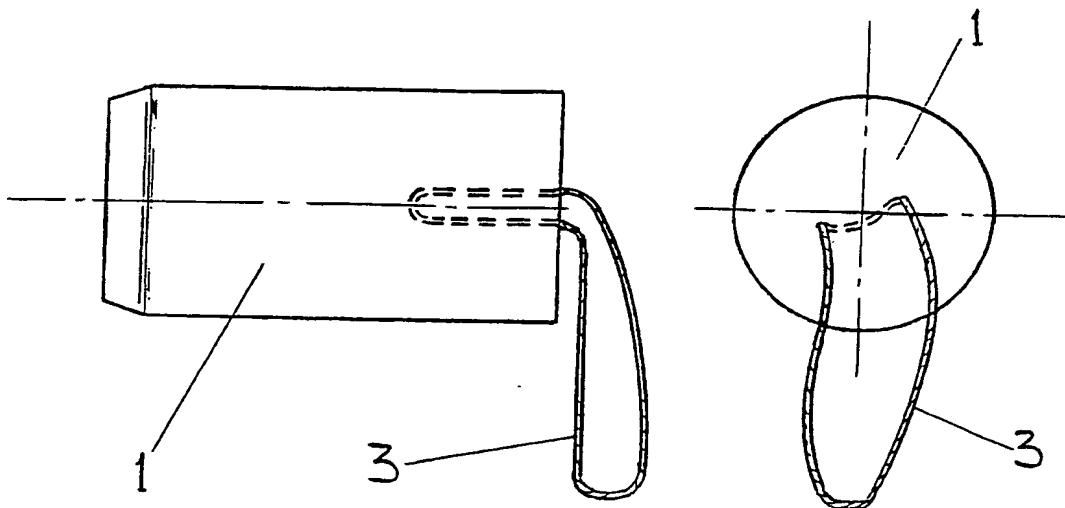
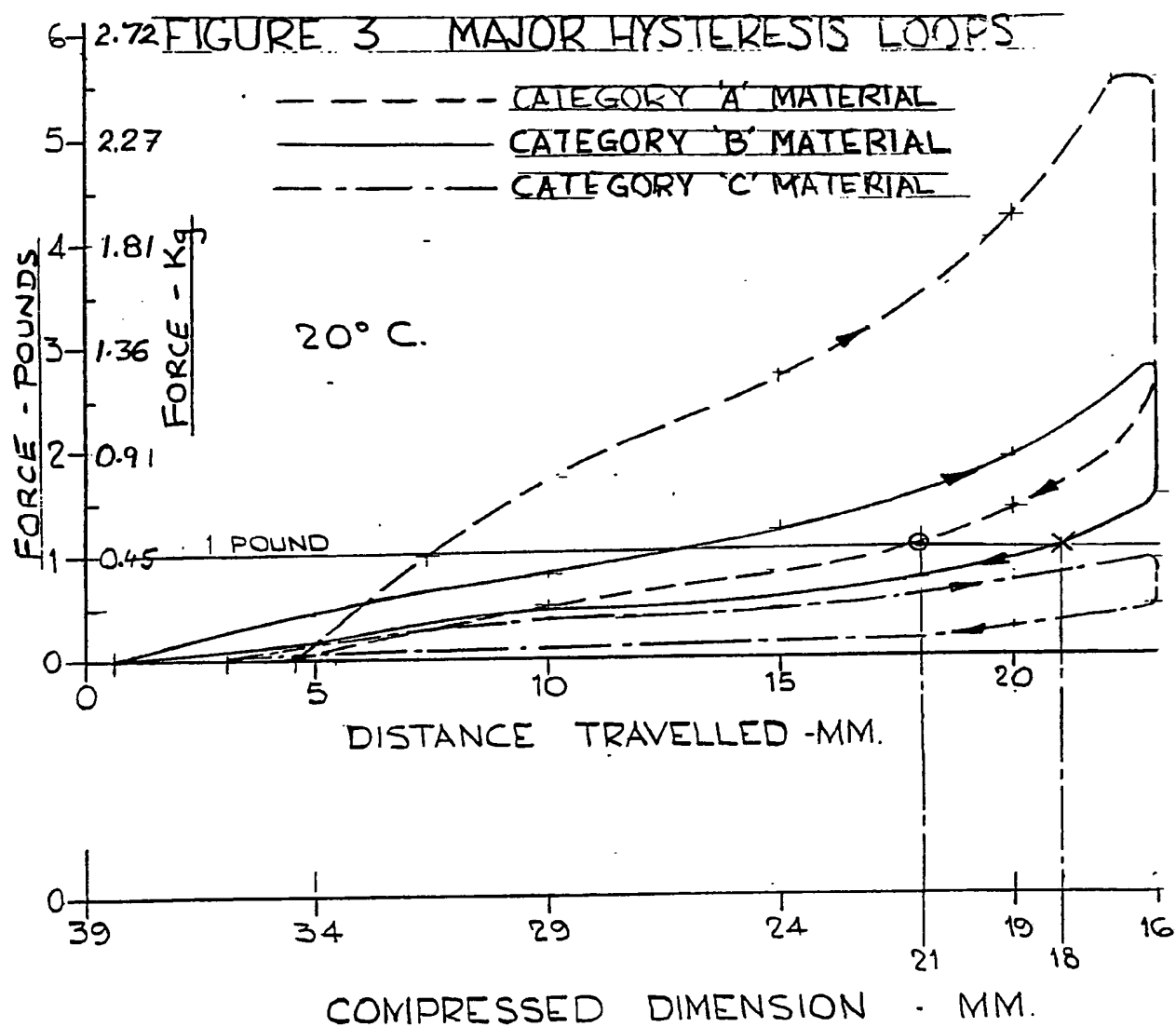
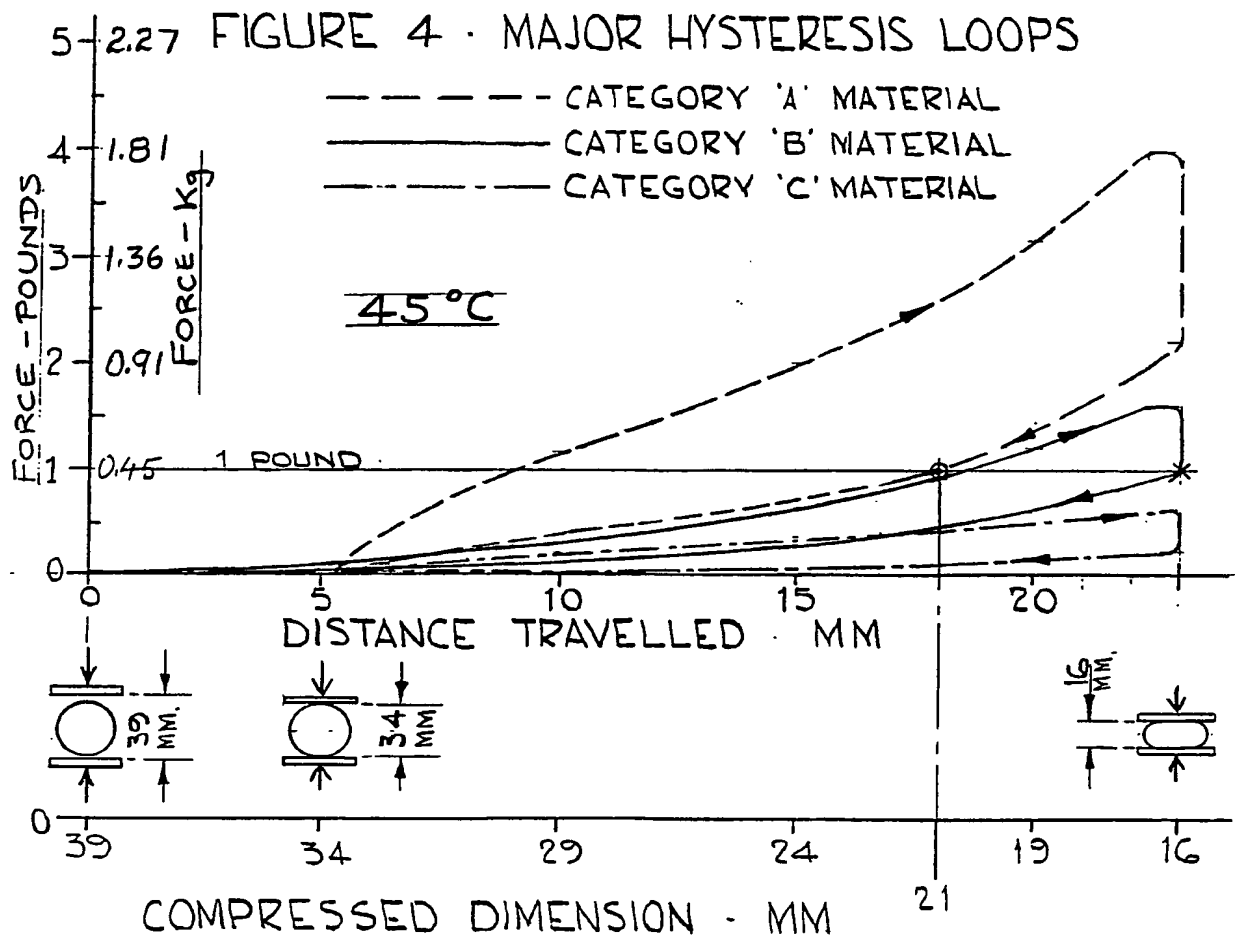


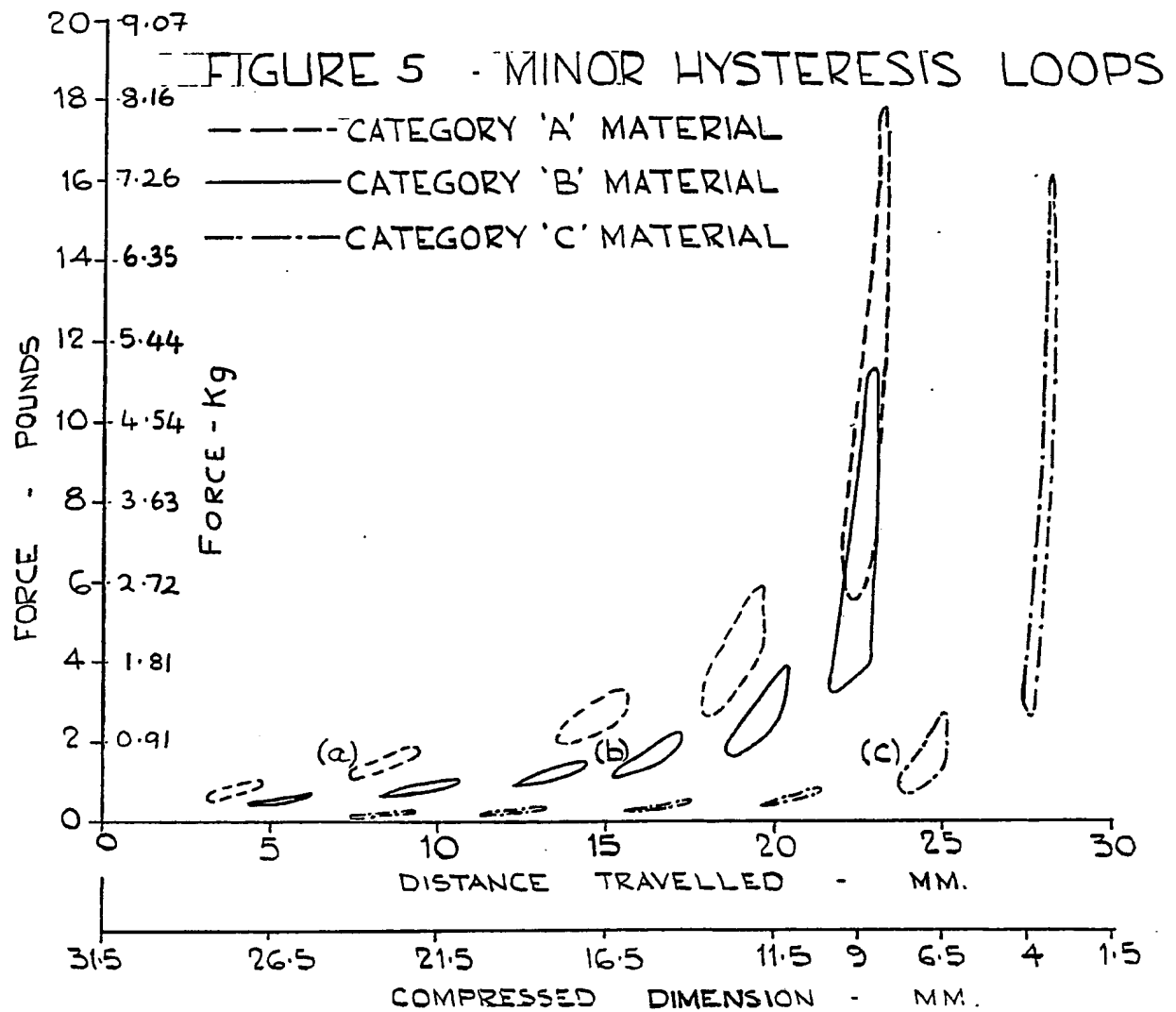
FIGURE 2



3/4




4/4



INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 88/00464

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁴ : A 61 F 2/48; A 61 F 13/20		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁴	A 61 F	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ⁹	Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	US, A, 4019498 (HAWTREY) 26 April 1977 see the whole document --	1
A	US, A, 2638093 (KULICK) 12 May 1953 see column 1, line 43 - column 5, line 37; figures --	1
A	EP, A, 0051709 (LANGLOIS) 19 May 1982 see page 3, line 25 - page 5, line 6; figure 1 --	1,5,7
A	US, A, 4467806 (BHIWANDIWALA) 28 August 1984 see column 2, lines 1-38; claim 12; figures 1,4 --	1,5,7
A	DE, A, 3139811 (HENNIG) 21 April 1983 --	
A	US, A, 4081884 (JOHST) 4 April 1978 --	
A	US, A, 3902493 (BAIER) 2 September 1975 cited in the application -----	
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
25th August 1988	14. 09. 88	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	 P.C.G. VAN DER PUTTEN	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

GB 8800464
SA 22793

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 08/09/88. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4019498	26-04-77	None	
US-A- 2638093		None	
EP-A- 0051709	19-05-82	None	
US-A- 4467806	28-08-84	EP-A, B 0168507	22-01-86
DE-A- 3139811	21-04-83	None	
US-A- 4081884	04-04-78	FR-A, B 2390155	08-12-78
		DE-A, C 2802101	23-11-78
		AU-A- 3245378	26-07-79
		GB-A- 1588581	23-04-81
		AU-B- 513113	13-11-80
		CH-A- 629382	30-04-82
		AT-B- 376563	10-12-84
US-A- 3902493	02-09-75	NL-A- 7505574	17-11-75
		BE-A- 828946	12-11-75
		FR-A, B 2270893	12-12-75
		DE-A- 2520595	27-11-75
		GB-A- 1506953	12-04-78
		CA-A- 1028101	21-03-78